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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,219	06/29/2000	Ivan Tomka	24301	7685

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EXAMINER
NORDMEYER, PATRICIA L

ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

AS-13

Office Action Summary	Application No.	Applicant(s)	
	09/606,219	TOMKA ET AL.	
	Examin r	Art Unit	
	Patricia L. Nordmeyer	1772	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-21 and 23-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12 and 22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

Withdrawn Rejections

1. The 35 U.S.C. 112 rejections of claims 12, 15, 16 and 18 – 21 of record in Paper #7, Pages 2 – 4, Paragraphs 2 – 5 have been withdrawn due to Applicant's amendment in Paper #11.

Repeated Rejections

2. The 35 U.S.C. 102 rejection of claims 12 – 14 as anticipated by Bastioli et al. is repeated for reasons previously of record in Paper # 7, Page 5, Paragraph 7.

Bastioli et al. discloses a starch composition containing 30 to 80% by weight amylopectin material with respect to the starchy and thermoplastic components (Column 3, lines 8 – 12), an organic softener made of 5 to 25% by weight of glycerine (Column 3, lines 44 – 51) and esters of fatty acids as release agents and lubricants (Column 4, lines 37 – 31). Since Bastioli et al. contains the selected materials of amylopectin and glycerine, it is inherent that the starch would have a viscosity of at least 40 ml/g.

3. The 35 U.S.C. 103 rejection of claim 15 over Bastioli et al. in view of Nakajima et al. is repeated for reasons previously of record in Paper # 7, Pages 5 – 6, Paragraph 9.

Bastioli et al. discloses the claimed starch mass above except for the mass containing

glycerine monostearate and lecithin in a weight ratio of 1:1.5, preferably 1:1.2, and even more preferred 1:1.

Nakajima et al. teaches a phospholipid, lecithin, (Column 3, lines 14 – 20) and glycerine monostearate as a nonionic surfactant (Column 3, lines 21 – 28) in a ratio of a phospholipid to surfactant of 9.5:0.5 to 1:9 (Column 3, lines 54 – 56) in a emulsified composition used for the administration of drugs for the purpose of incorporating the drug quickly into the body from the blood stream of the patient.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the lecithin and glycerine monostearate in Bastioli et al. in order to incorporate the drug quickly into the body from the blood stream of the patient as taught by Nakajima et al.

Nakajima et al. discloses the claimed invention except for the weight ratio of 1:1.5, preferably 1:1.2, and even more preferred 1:1 of glycerine monostearate and lecithin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the weight ratio of the glycerine monostearate and lecithin, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges through routine experimentation depending on the end results involves only routine skill in the art. *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980).

4. The 35 U.S.C. 103 rejection of claims 16, 17 and 21 over Bastioli et al. in view of Wittwer et al. is repeated for reasons previously of record in Paper # 7, Pages 6 – 7, Paragraph 10.

Bastioli et al. discloses the claimed starch mass above except for the mass additionally containing an aggregate in a weight range of 3.5% by weight to 15% by weight with respect to the total weight of the mass, preferably of 5% by weight to 8% by weight, wherein the aggregate is selected from the group consisting of carbonates and/or hydrogen carbonates of alkali and/or earth alkali ions, preferably calcium carbonate, amylases, further decomposing agents colorings, preservatives, antioxidants, physically and/or chemically modified biopolymers and vegetable polypeptides, a shape body manufactured from a mass according to claim 12 and wherein the shape body consists of a multi-layered film and that at least two of the films have a different composition.

Wittwer et al. teaches films containing starches, plasticizers, lubricants and colorings in concentrations of 0.001 to 10% based on the weight of the starch (Column 13, lines 63 – 67) in capsules (Column 13, lines 42 – 47) for the purpose of packaging drugs in colored capsules that help identify the drugs before being ingested by the patients.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the colorings with the selected weight percentage in

Bastioli et al. in order to packaging drugs in colored capsules that help identify the drugs before being ingested by the patients as taught by Wittwer et al.

5. The 35 U.S.C. 103 rejection of claims 18 – 20 over Bastioli et al. in view of Wittwer et al. and further in view of Bastioli et al. is repeated for reasons previously of record in Paper # 7, Pages 7 – 8, Paragraph 11.

Bastioli et al ('980) , as modified with Wittwer et al., discloses the claimed invention except for an elongation of rupture of at least 100%, preferably at least 160%, and even more preferred 240% at 25 C and 60% relative air humidity, the body shape with a strength of at least 2 MPa, preferably a strength in the range of 3.5 MPa to 8 MPa and even more preferred from 4 MPa to 6.5 MPa and a capsule with a thickness between 0.1 and 2mm, preferably between 0.2 and 0.6 mm.

Bastioli et al. ('692) teaches a breaking strain of 207%, a breaking stress of 21 MPa, both at a temperature of 23 C and 55% relative humidity (Column 48 – 59) and a thickness of 0.02mm (Column 4, lines 11 – 12) in a film or molded article formed of starch containing amylopectin for the purpose of forming a biodegradable film or article with good chemical, mechanical and chemical properties.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the breaking strain, breaking stress and thickness in the

modified Bastioli et al. ('980) in order to form a biodegradable film or article with good chemical, mechanical and chemical properties as taught by Bastioli et al. ('692).

Bastioli et al. ('692). discloses the claimed invention except for the thickness between 0.1 and 2mm and the strength between 2 and 8 MPa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the thickness of the film which would affect the strength, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges through routine experimentation depending on the end results involves only routine skill in the art. *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980).

New Rejections

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bastioli et al. (USPN 5,462,980).

Bastioli et al. discloses a starch composition containing 30 to 80% by weight amylopectin material with respect to the starchy and thermoplastic components (Column 3, lines 8 – 12), an

organic softener made of 5 to 25% by weight of glycerine (Column 3, lines 44 – 51) and esters of fatty acids as release agents and lubricants (Column 4, lines 37 – 31). Since Bastioli et al. contains the selected materials of amylopectin and glycerine, it is inherent that the starch would have a viscosity of at least 40 ml/g.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bastioli et al. in view of Nakajima et al. (USPN 5,098,606).

Bastioli et al. discloses the claimed starch mass above except for the mass containing glycerine monostearate and lecithin in a weight ratio of 1:1.2 or a weight ratio of 1:1.

Nakajima et al. teaches a phospholipid, lecithin, (Column 3, lines 14 – 20) and glycerine monostearate as a nonionic surfactant (Column 3, lines 21 – 28) in a ratio of a phospholipid to surfactant of 9.5:0.5 to 1:9 (Column 3, lines 54 – 56) in a emulsified composition used for the administration of drugs for the purpose of incorporating the drug quickly into the body from the blood stream of the patient.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the lecithin and glycerine monostearate in Bastioli et al. in order to incorporate the drug quickly into the body from the blood stream of the patient as taught by Nakajima et al.

Nakajima et al. discloses the claimed invention except for the weight ratio of 1:1.5, preferably 1:1.2, and even more preferred 1:1 of glycerine monostearate and lecithin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the weight ratio of the glycerine monostearate and lecithin, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges through routine experimentation depending on the end results involves only routine skill in the art. *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980).

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bastioli et al. in view of Wittwer et al. (USPN 4,673,438).

Bastioli et al. discloses the claimed starch mass above except for the mass additionally containing an aggregate in a weight range of 5% by weight to 8% by weight.

Wittwer et al. teaches films containing starches, plasticizers, lubricants and colorings in concentrations of 0.001 to 10% based on the weight of the starch (Column 13, lines 63 – 67) in

capsules (Column 13, lines 42 – 47) for the purpose of packaging drugs in colored capsules that help identify the drugs before being ingested by the patients.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the colorings with the selected weight percentage in Bastioli et al. in order to packaging drugs in colored capsules that help identify the drugs before being ingested by the patients as taught by Wittwer et al.

11. Claims 28 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bastioli et al. (USPN 5,462,980) in view of Wittwer et al. (USPN 4,673,438) as applied to claims 16, 17 and 21 above, and further in view of Bastioli et al. (USPN 5,569,692).

Bastioli et al. ('980), as modified with Wittwer et al., discloses the claimed invention except for an elongation of rupture of at least 160%, and at least 240% at 25 C and 60% relative air humidity, the body shape with a strength in the range of 3.5 MPa to 8 MPa or from 4 MPa to 6.5 MPa and a capsule with a thickness between 0.1 and 2mm or 0.2 and 0.6 mm.

Bastioli et al. ('692) teaches a breaking strain of 207%, a breaking stress of 21 MPa, both at a temperature of 23 C and 55% relative humidity (Column 48 – 59) and a thickness of 0.02mm (Column 4, lines 11 – 12) in a film or molded article formed of starch containing amylopectin for the purpose of forming a biodegradable film or article with good chemical, mechanical and chemical properties.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the breaking strain, breaking stress and thickness in the modified Bastioli et al. ('980) in order to form a biodegradable film or article with good chemical, mechanical and chemical properties as taught by Bastioli et al. ('692).

Bastioli et al. ('692). discloses the claimed invention except for the thickness between 0.1 and 2mm and the strength between 2 and 8 MPa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the thickness of the film which would affect the strength, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges through routine experimentation depending on the end results involves only routine skill in the art. *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980).

Response to Arguments

12. Applicant's arguments filed in Paper #11 regarding the 35 U.S.C. 102 rejection of claims 12 – 14 as anticipated by Bastioli et al. have been fully considered but they are not persuasive.

In response to Applicant's arguments that Bastioli et al. fail to teach a homogenized starch-containing mass, the recitation that the starch-containing mass is homogenized has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the

preamble is a self-contained description of the structure not depending for completeness upon the introductory clauses. *Kropa v. Robie,* 88 USPQ 478 (CCPA 1951).

13. Applicant's arguments filed in Paper #11 regarding the 35 U.S.C. 103 rejection of claim 15 over Bastioli et al. in view of Nakajima et al. have been fully considered but they are not persuasive.

In response to Applicant's arguments that Bastioli et al. and Nakajima et al. fail to teach a homogenized starch-containing mass, the recitation that the starch-containing mass is homogenized has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clauses. *Kropa v. Robie,* 88 USPQ 478 (CCPA 1951).

In response to Applicant's argument that Bastioli et al. includes additional structure not required by Applicant's invention, it must be noted that Bastioli et al. discloses the invention as claimed. The fact that it discloses additional structure not claimed is irrelevant.

In response to Applicant's argument that Bastioli fails to disclose a material which can be used for the formation of soft capsules, it has been held that a recitation with respect to the manner in which a claimed articles is intended to be employed does not differentiate the claimed

apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham,* 2 USPQ 2d 1647 (1987). The claim does not refer a capsule but a starch mass.

In response to Applicant's argument that the polymeric compounds used in Bastioli et al. formulations will not dissolve under conditions occurring in the human stomach and/or intestinal tract, applicant misinterprets the principle that claims are interpreted in the light of the specification. Although these elements (dissolvable polymeric compositions) are found as examples or embodiments in the specification, they were not claimed explicitly. Nor were the words that are used in the claimed defined in the specification to require these limitations. A reading of the specification provides no evidence to indicate that these limitations must be imported into the claims to give meaning to disputed terms. *Constant v. Advanced Micro-Devices, Inc.,* 7 USPQ 2d 1064.

14. Applicant's arguments filed in Paper #11 regarding the 35 U.S.C. 103 rejection of claims 16, 17 and 21 over Bastioli et al. in view of Wittwer et al. have been fully considered but they are not persuasive.

In response to Applicant's arguments that Bastioli et al. and Wittwer et al. fail to teach a homogenized starch-containing mass, the recitation that the starch-containing mass is homogenized has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the

claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clauses. *Kropa v. Robie,* 88 USPQ 478 (CCPA 1951).

15. Applicant's arguments filed in Paper #11 regarding the 35 U.S.C. 103 rejection of claims 18 - 20 over Bastioli et al. in view of Wittwer et al. and further in view of Bastioli et al. have been fully considered but they are not persuasive.

In response to Applicant's arguments that Bastioli et al. and Wittwer et al. fail to teach a homogenized starch-containing mass, the recitation that the starch-containing mass is homogenized has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clauses. *Kropa v. Robie,* 88 USPQ 478 (CCPA 1951).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Nordmeyer whose telephone number is (703) 306-5480. The examiner can normally be reached on Mon.-Thurs. from 7:00-4:30 & alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on (703) 308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Patricia L. Nordmeyer
Examiner
Art Unit 1772

pln
December 31, 2002

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

1/10/03